Results of Canadian Ecological Categorization of the DSL and Next Steps

Nicole Davidson

GLBTS Integration Workgroup Meeting

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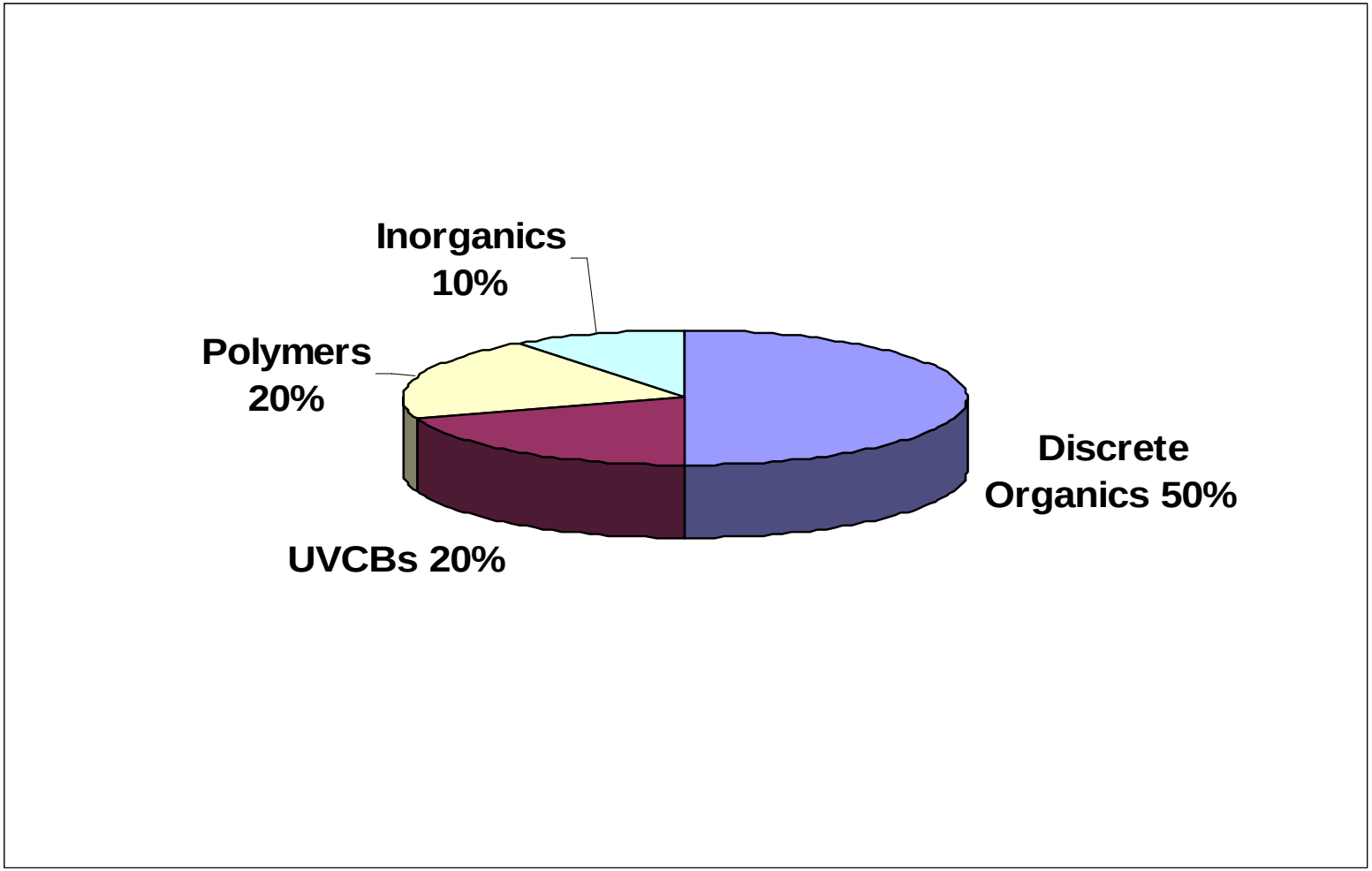
Canada

What is the Domestic Substances List (DSL)?

- A list of substances that are “in commerce” in Canada – “existing substances”
- The DSL was created in 1991 for the purpose of defining a “new substance”
- For categorization, focussing on substances nominated as being, between 1984-1986:
  - In Canadian commerce or used for commercial manufacturing in Canada, or;
  - Manufactured or imported in Canada at >100 kg/year
  - Does not include: contaminants, by-products and wastes.

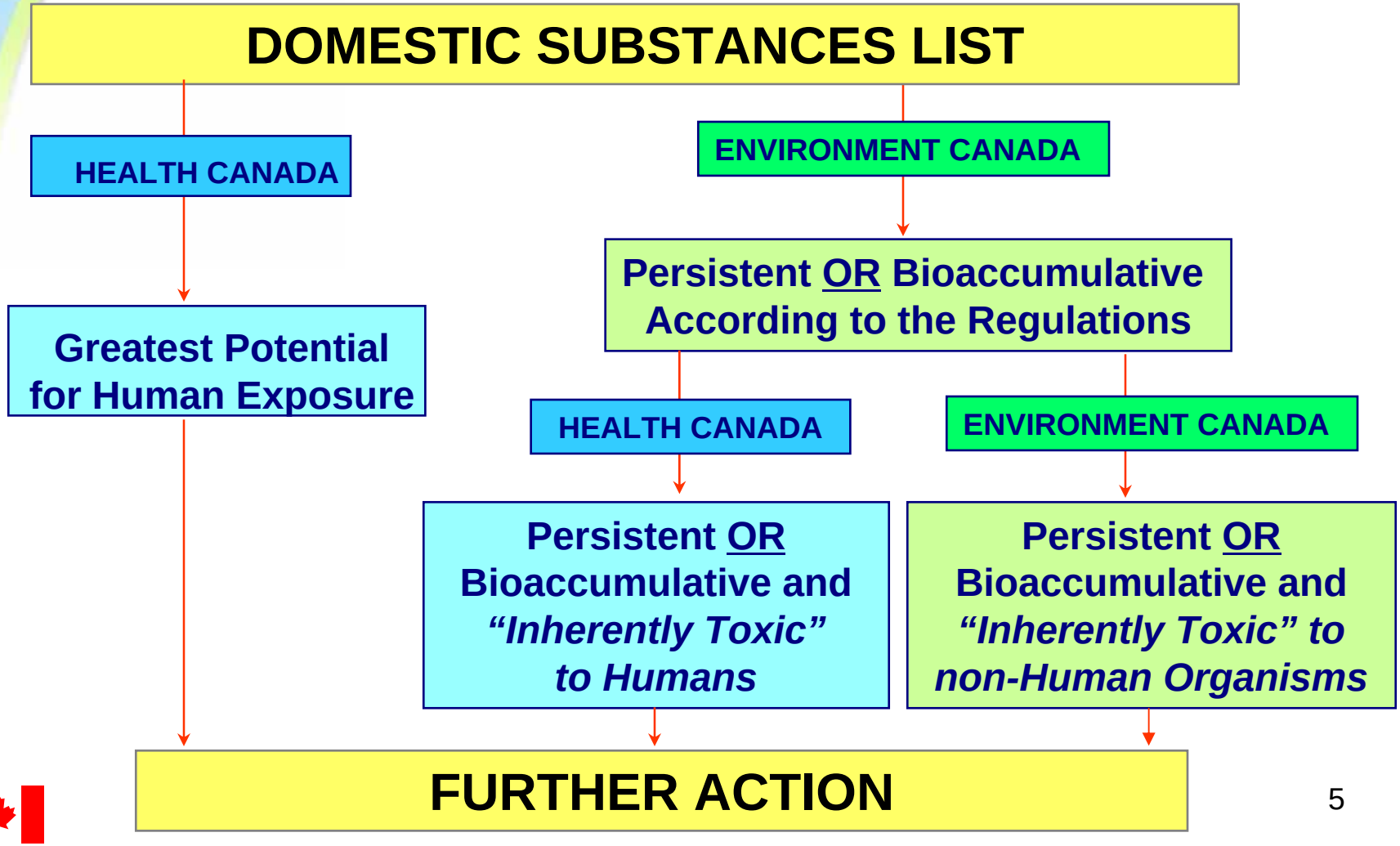
Types of Substances on the DSL (total 23,000 substances)



Categorization is mandated under Canadian Environmental Protection Act (CEPA 1999)

- Ministers of Environment and Health are required to categorize the 23,000 substances on the Domestic Substances List by September 14, 2006
- Categorization is a **priority setting** exercise that involves the systematic identification of substances on the DSL that should be subject to screening assessment
- This includes identifying substances, based on available information that:
  - May present, to individuals in Canada, the greatest potential for exposure (GPE); or
  - Are persistent (P) or bioaccumulative (B), in accordance with the P and B regulations, and inherently toxic (iT) to humans or to non-human organisms, as determined by lab or other studies

Categorization of Substances on the DSL: Operational Approach



Categorization Criteria for P, B, and non-human iT

Bioaccumulation

BAF $\geq$ 5000
or
BCF $\geq$ 5000
or
log Kow $\geq$ 5

iT –non-humans

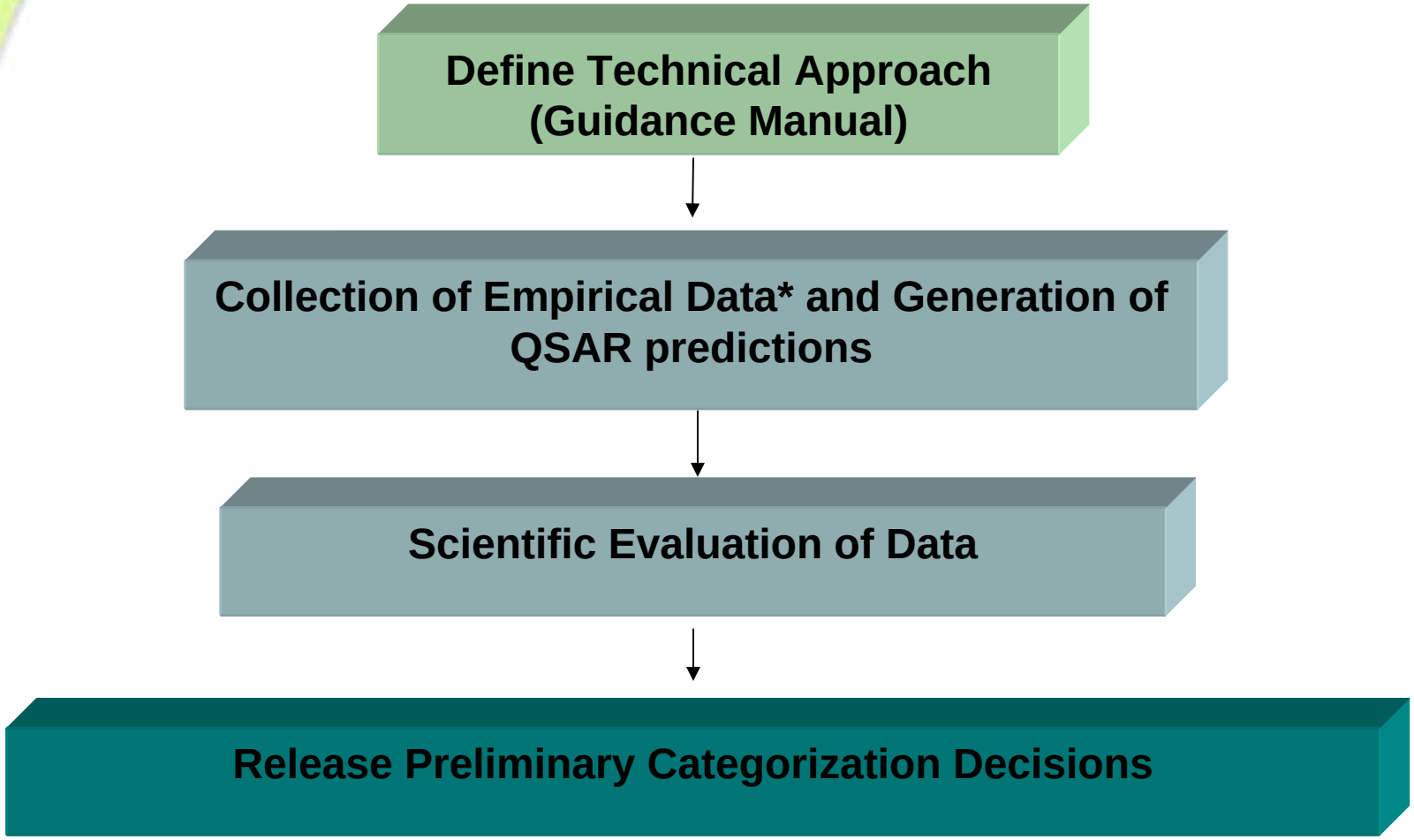
Acute aquatic toxicity of $LC(EC)_{50} \leq$ 1mg/L, or a chronic aquatic toxicity of NOEC $\leq$ 0.1 mg/L

Persistence

A substance is considered persistent if its transformation half-life satisfies the criterion in any one environmental medium or if it is subject to long-range transport

Medium	Half-life
Air	$\geq$ 2 days (or LRT)
Water	$\geq$ 6 months
Sediment	$\geq$ 1 year
Soil	$\geq$ 6 months

Process for Ecological Categorization



Process for Ecological Categorization

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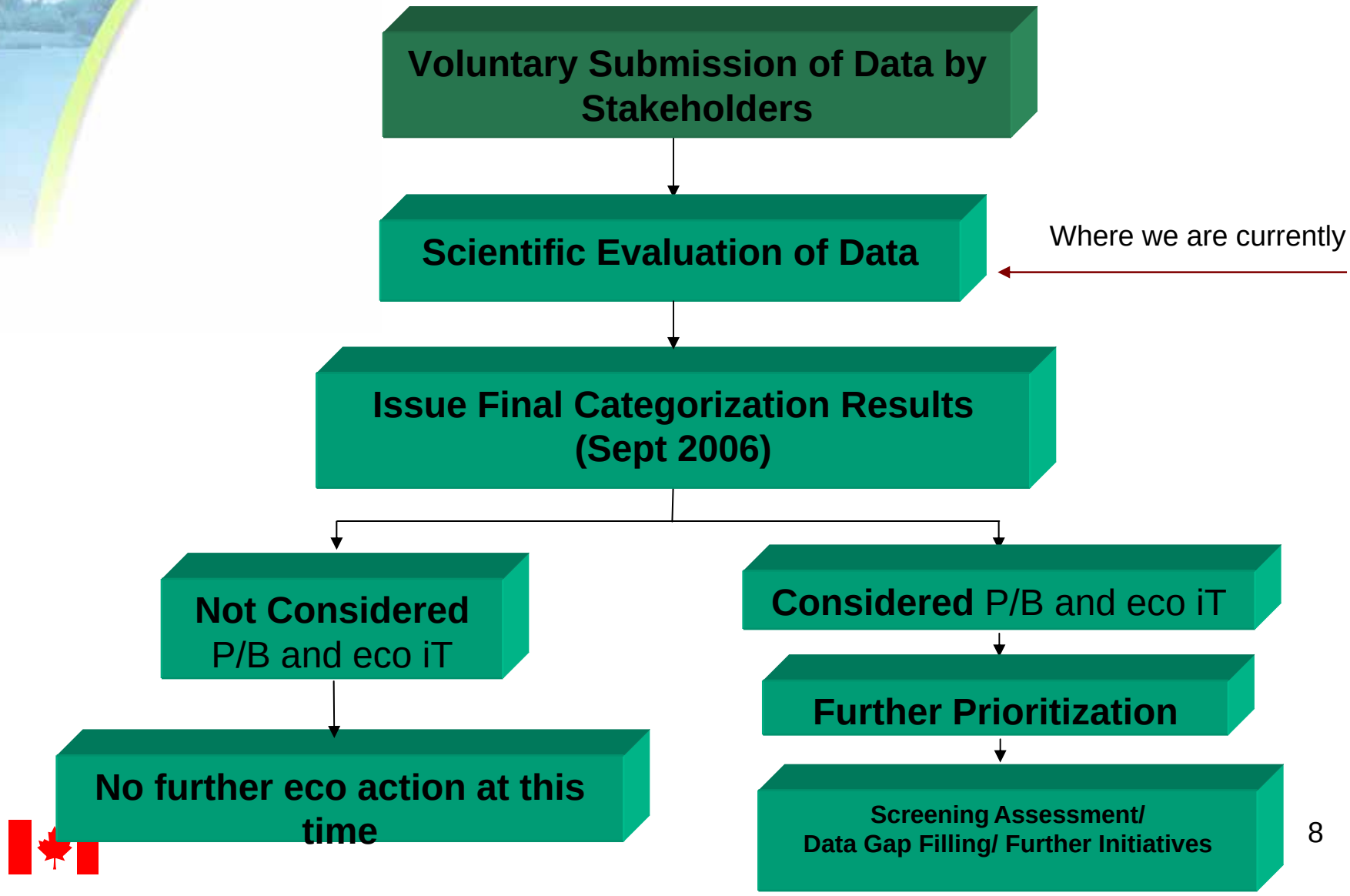

Availablility of P, B and iT Data – Organics Example

- Of the ~11500 organic substances under consideration, categorization has identified:
  - ~1200 substances with experimental aquatic toxicity data (4/5 of which was of acceptable quality);
  - ~425 substances with bioaccumulation/ bioconcentration experimental data (4/5 of which was of acceptable quality);
  - ~1500 substances with persistence experimental data (2/3 of acceptable quality).

Stakeholder Submission of Data

- June 2004, Canada launched an 18 month voluntary challenge to industrial stakeholders and interested parties to submit experimental study or other information that could help refine categorization decisions

- So far, we have received approx 20 larger data submissions for consideration and 375 individual studies addressing P, B or aquatic toxicity

- Approx. 20 submissions have been received covering the human health aspects of categorization

Data Preference for P B iT Profiles

Preference	P	B	iT
Higher	Experimental		
Medium	Analogue / Groupings / Scientific rationale		
Lower	Modelled (QSAR)		

Ecological Aspects of Categorization Results to Date:

Of the 22,400 substances for which we have preliminary categorization decisions, there is evidence that:

- 3788 meet ecological categorization criteria (April CD)
  - ~ 400 PBiT
  - ~ 500 High volume PiT or BiT
  - ~ 1600 Medium Volume PiT or BiT
  - ~ 1100 Low Volume PiT or BiT (<1000kg)
  - ~ 100 PiT or BiT unknown volume
- A further 1500 substances are Uncertain because they have no data or data is conflicting
- Exposure/entry information not considered at this point

Further Priority Setting

- A large number of substances meet the criteria for categorization so further prioritization will be required
- While assessment is the appropriate next step for some substances; it is not appropriate for all substances
- Based on the information collected through categorization, the following additional **actions** have been identified:
  - Data gap filling/Research
  - Cooperation with other initiatives and jurisdictions
  - Preventative risk management
- The **highest ecological priorities** for action include:
  - Substances that are inherently toxic, and both persistent **and** bioaccumulative (PBiT) (~ 400 subs)

Priorities - PBiT Substances

423 PBiT Substances:

- ~ 40 already assessed or managed
- 171 based on experimental or analogue/grouping data (higher confidence in data)
- 4 based on mix of experimental/analogue/grouping/modelled data (medium confidence)
- 249 based on modelled data (some analogue) (lower confidence in data)

Preliminary Action being taken:

- S.71 Survey Notice issued in Canada Gazette on March 4, 2006
- Survey designed to 1) Identify which substances are in commerce in Canada and 2) Identify stakeholders and sectors before further action is taken on these substances

Chemicals Management and Categorization: the broader context

- Canada's categorization work is a "world first" in addressing the legacy of existing substances
- The assessment and better management of chemical risks is a **global problem**. No jurisdiction has had a good information base about the many thousands of substances that were in commercial use before the new substance requirements came into place.
- Canada is working toward positioning the results of categorization in the context of a **broader chemicals management framework**. At its core is the recognition of the need to promote greater consistency in assessment and management practices, and to eliminate unnecessary costs and duplication of work for governments and industry alike.
- We see categorization as an opportunity to revisit our policy, and to develop a stronger, more coherent regime that makes the best use of strengths of all government jurisdictions and authorities, and increases the role of chemical users and producers in identifying and preventing potential risks to the health of Canadians and the Environment.

What is next for Existing Substances that meet the categorization criteria?

- **Report results** of categorization within the context of the broader chemicals management framework
- Develop a mechanism to **group substances** according to the anticipated post-categorization actions of government, industry and stakeholders
- Challenge stakeholders to provide **additional data** that are not publicly available
- Develop a long-term plan to engage the **research community** to support priorities by filling data gaps and identifying emerging trends for new and existing substances of concern
- Align the domestic program with **international initiatives**.
- Recognize initiatives undertaken by **stakeholders** who want to play a **leadership role**

- **We will be consulting with stakeholders over the coming months on the work following categorization and how we manage chemicals in a broader context**